K012370

AUG - 3 2001

510(k) SUMMARY

Invacare Corporation's
Model Solara Jr. Manual Wheelchair

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person: Rae Ann Farrow
Manager, Regulatory Compliance

Date Prepared: July 25, 2001

Name of Device and Name/Address of Sponsor

Model Solara Jr. Manual Wheelchair
Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical 89IOR

Predicate Devices
The Invacare Solara Jr. is substantially equivalent to the Model "Action AT II" Manual Wheelchair **(K984447, 1/8/99)** and the "Action Wizard" Manual Wheelchair **(K934646, 12/15/93)**.

Intended Use: The intended use of the Solara Jr. Manual Wheelchair is to provide mobility to children limited to a sitting position.

Technological Characteristics and Substantial Equivalence

Device Description The Invacare Corporation Model Solara Jr. is a manually operated, attendant propelled, manual, mechanical wheelchair. It's intended function and use is to

provide mobility to children who may need very specialized seating systems and tilt to assist in positioning and feeding.

The product consists of an aluminum frame, various options of rear wheel sizes, and smaller front pivoting casters for steering and turning. The product is designed to be a lightweight, user adaptable, everyday wheelchair, for both indoor and outdoor use. This device is a rigid, non-folding type of wheelchair that incorporates a solid seating surface. This type of seat makes the chair easily adaptable to the various types of wheelchair cushions and seating systems currently available in the market. The upholstery, when provided by Invacare, meets the requirements of both the California Bureau of Home Furnishings 116 and 117 and the Boston Fire Department IX –1 Flammability Standards.

The Solara Jr. frame is constructed from aluminum tubing that is tig-welded. The frame is also secured with fasteners to allow the size of the chair to be adjusted as needed to accommodate the growth of the child. The homecare dealer can make many of the changes without additional parts.

The Solara Jr. also includes a "Tilt in Space" feature, which allows the seat and the back of the wheelchair to be tilted. This feature is used for those patients who require a tilt feature to help in positioning, comfort, or head control. It also serves as an attendant aid in those situations where the patient needs to be tilted, in order to be fed or attended to in some fashion. The Solara Jr. is primarily for attendant propelling. The attendant version of the chair is available with stroller type push handles for ease of attendant pushing and the optional stroller handles allows the attendant to push the chair while the occupant is tilted.

The "Tilt in Space" feature is manually operated and consists of two linear slides allowing the seat to tilt through a 50 degree range with little change in the overall center of gravity of the chair and the occupant. The tilting operation is initiated when the caregiver depresses the levers attached to the push handles. The levers in turn actuate cables that disengage a pair of latch mechanisms mounted to two of the frame rails. Once the desired tilt angle has been obtained, the handles are released and the chair will remain at the angle chosen. The seat tilt range is from –5 degrees anterior through 45 degrees posterior.

The chair also has a recline only operation which changes the angle between the seat pan and the back of the chair. The chair is reclined by pulling up on the handles of the recliner cable assemblies to activate the gas cylinders and then slowly squeezing the handles of the recliner cables assemblies and allowing the back to recline at the desired angle. When the back is at the desired angle the handles are released.

Substantial Equivalence The Invacare Solara Jr. is substantially equivalent to the Model "Action AT II" Manual Wheelchair **(K984447, 1/8/99)** and the "Action Wizard" Manual Wheelchair **(K934646, 12/15/93)**.

Performance Data

The Invacare Solara Jr. Manual Wheelchair meets the applicable performance requirements specified in:

- Rehabilitation Engineering Society of North America (RESNA) Standard ANSI/RESNA WC/Vol.1-1998 "Requirements and Test Methods for Wheelchairs (Including Scooters).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2001

Ms. Rae Ann Farrow
Manager, Regulatory Compliance
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44035

Re: K012370
Trade/Device Name: Invacare Model Solara Jr. Manual Wheelchair
Regulation Number: 890.3850
Regulatory Class: I
Product Code: IOR
Dated: July 25, 2001
Received: July 26, 2001

Dear Ms. Farrow:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~TBD~~ K012370

Device Name: *Invacare Model Solara Jr. Manual Wheelchair*

Indications For Use:

The intended use of the Invacare Model Solara Jr. Manual Wheelchair is to provide mobility to children limited to a sitting position.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **OR** **Over-The-Counter Use** √
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012370

(Optional Format 1-2-96)